



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857
Re: Surpass
Docket No.: 2004E-0389

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

JAN - 6 2006

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 4,937,078, filed by Mezei Associates, Ltd., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Surpass, the animal drug product claimed by the patent.

The total length of the regulatory review period for Surpass is 2,262 days. Of this time, 1,028 days occurred during the testing phase and 1,234 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 512(j) of the Federal Food, Drug, and Cosmetic Act involving this animal drug product became effective: March 6, 1998.

The applicant claims January 11, 1999, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the date of FDA's official acknowledgement letter assigning a number to the INAD was March 6, 1998, which is considered to be the effective date for the INAD.

2. The date the application was initially submitted with respect to the animal drug product under subsection 512(b) of the Federal Food, Drug, and Cosmetic Act: December 27, 2000.

The applicant claims January 2, 2001, as the date the new animal drug application (NADA) for Surpass (NADA 141-186) was initially submitted. However, a review of FDA records reveals that NADA 141-186 was initially submitted on December 27, 2000.

3. The date the application was approved: May 13, 2004.

FDA has verified the applicant's claim that NADA 141-186 was approved on May 13, 2004.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jane A. Axelrad". The signature is fluid and cursive, with the first name "Jane" being the most prominent.

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Paul E. Dietze
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